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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/680,996

10/07/2003

William G. Tatton

17530 (AP)

6653

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02/14/2008

EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

02/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/680,996	Applicant(s) TATTON ET AL.	
	Examiner Renee Claytor	Art Unit 1617	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 January 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____.
- Claim(s) objected to: _____.
- Claim(s) rejected: 1-10.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

Applicant's arguments over both 35 U.S.C. § 112, first paragraph rejections have been considered but are not found to be persuasive. Applicant's argument over the first rejection is that the specification is enabled for the treatment of all neurodegenerative disorders with brimonidine and that it is stated at paragraph 35, elaborated at paragraphs 43-47 and experiments described in paragraphs 84-110. It is noted that the Applicant states that the invention is drawn to brimonidine treating neurodegenerative disorders. However, in paragraphs 43-47 Applicant's discuss that brimonidine protects neural cells of the brain against damage and death but there is no data supporting the statement that brimonidine is an effective treatment for all neurodegenerative disorders, such as multiple sclerosis or ALS. Further, Applicant's state that the experiments outlined in paragraphs 84-110 support the statement that brimonidine treats all neurodegenerative disorders. This is not persuasive because the experiments support the treatment of Parkinson's disease with brimonidine, but not any other neurodegenerative disorder. Appropriate experiments outlining the administration of brimonidine for the treatment of various neurodegenerative conditions would be necessary to make the determination.

Applicant's arguments over the second 35 U.S.C. § 112, first paragraph rejection is that it is stated in the specification that the invention is directed to methods for preventing death or degeneration of neural cells by administration of brimonidine and that this is stated in paragraphs 35-36 and details of the treatment in paragraphs 43-47. More specifically, Applicants point out experiments outlined in paragraphs 94-110 exemplify that animals treated with MPTP and brimonidine lose fewer neurons than administration of brimonidine alone. The specification does not outline any experiment which exemplifies that brimonidine would prevent neuron death altogether, but exemplifies brimonidine as decreasing the amount of neuron death that occurs. Experimentation would require reasonable anticipation that neuron death, such as that associated with Parkinson's disease for example, is going to occur and that administration of brimonidine would hinder this neuron death from ever occurring.

Applicant's arguments over the 35 U.S.C. § 103 rejections have been considered and are not found to be persuasive. Applicant's argue that neither the Arnsten or Olejnik reference suggests that brimonidine (or clonidine as taught by Arnsten) prevent neuron death or degeneration and that it is one thing to cause memory improvement and another thing to prevent neuron death. In response to this argument, and to elaborate further in the discussion of preventing neuron death discussed above, the prior art does not support the claim of "preventing" neuron death. Prevention of neuron death would require anticipating that patient is going to have a particular disorder, such as Parkinson's disease, and administering a treatment before the disease even occurs. As discussed in the Kedar reference given in the modified rejections below, prevention strategies would require knowledge of the risk factors, and sufficient risk factors have not been identified for such diseases such as Parkinson's disease. As is further taught by Kedar, treatment strategies aid in protecting neurons from further damage in the early phase of the disease and reduce the rate of progression of symptoms (see pg. 236, first paragraph). Therefore, treatment involving clonidine would obviously treat neurons and help to slow the progression of any further neuron damage and meets the limitation of the present claims. In addition to this argument, Applicant's argue that there is no evidence that brimonidine would prevent a neurodegenerative condition (referring to amended claim 1). This point is discussed in the new 35 U.S.C. 112 first paragraph rejection given below in which it is discussed that there is no support for the claim of "preventing" a neurodegenerative condition, only for the treatment of a neurodegenerative condition.

Applicant's arguments over the second 35 U.S.C. § 103 rejection have been considered and are not found persuasive. Applicant argues that none of the references cited suggests that any agent can prevent neurons from dying or degenerating. As discussed above, prevention of neuron death would require anticipation that neuron death is going to occur. The prior art teaches treatment of Parkinson's disease for example; therefore, neurons would obviously be treated to slow any further progression of neuronal damage in Parkinson's disease. The Applicant argues that there is no evidence that treating Parkinson's and Alzheimer's occurs via the same mechanism. However, the relation is pointed out in that Chan-Palay et al. teach that the locus ceruleus is an important source of norepinephrine and is implicated in Parkinson's and Alzheimer's disease and Arnsten et al. and Olejnik et al. teach that cell deterioration occurs in the locus ceruleus in Alzheimer's disease and alpha-2-receptor agonists are a beneficial treatment. Because the combined references teach that both diseases have similar pathologies, one would have a reasonable expectation of success that an alpha-2-receptor agonist would effectively treat both Alzheimer's and Parkinson's disease.

Applicant's arguments regarding new claim 10, which is directed to a method of treating Parkinson's disease by stating that the cited references do not teach or suggest brimonidine or any other compound, can be used to treat "cell deterioration". However, this limitation is not addressed in new claim 10, which is merely drawn to a method of treating Parkinson's disease comprising administration of brimonidine.

The Obvious Double Patenting rejection is being maintained for the reasons of record as Applicant put forth no arguments against the rejection.